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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,500	03/18/2005	Silvia Berlanga de Moraes Barros	ABARR.0101	4409

22858 7590 08/01/2008
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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
08/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,500	DE MORAES BARROS ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-30* is/are pending in the application.

4a) Of the above claim(s) *14-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 June 2008 has been entered.

Applicants state within their 02 June 2008 response that claims 14-23 have been withdrawn and new claims 24-30 have been added. As a formal matter, please note that claims 14-23 should have been canceled (not withdrawn), since only the Examiner can withdraw claims from consideration. Accordingly, claims 14-23 should be formally canceled in response to this Office action.

Claims 24-30 (as presented within the amendment filed 05 February 2008) are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 25 and 29 recite the phrase "wherein the 4-nerolidylcatechol is naturally occurring". This phrase is deemed new matter as the only support the Examiner could find with respect to the 4-nerolidylcatechol being "naturally occurring" is whereby the compound is within an extract of *Pothomorphe umbellata*, but not "naturally occurring" in the sense of the compound being present within any and all extracts or other natural materials that may contain the recited compound therein. Accordingly, the phrase "wherein the 4-nerolidylcatechol is naturally occurring" is a broader concept than what the instant specification provides for and is, therefore, deemed new matter.

Claims 26 and 30 recite the phrase "the 4-nerolidylcatechol is extracted from *Pothomorphe umbellata*" which is deemed new matter as the Examiner could find nowhere within the instant disclosure (including the original claims) which support a gel composition which comprises 4-nerolidylcatechol (*per se*) other than in the form of a *Pothomorphe umbellata* extract which contains the percentage of 4-nerolidylcatechol therein. That is, as originally claimed and disclosed by the instant specification, the 4-nerolidylcatechol is present within such a composition only in the form *Pothomorphe umbellata* extract (i.e., a "standardized extract") which contains this compound therein (within the recited percentage amounts) - but not in the form of an isolated compound taken (extracted) from the *Pothomorphe umbellata* plant - as defined by the cited phrase within new claims 26 and 30.

In claim 28, the newly recited phrase "administration of a gel of the composition: ..." because this phrase apparently is drawn to administering a gel consisting of (which is closed language) of the list of ingredients that follow the colon symbol: including 4-nerolidylcatechol (within the recited percentage amounts). However, as discussed above, the Examiner could find nowhere within the instant disclosure (including the original claims) which support a gel composition which comprises or consist of 4-nerolidylcatechol (*per se*) other than in the form of a *Pothomorphe umbellata* extract which contains the percentage of 4-nerolidylcatechol therein. That is, as originally claimed and disclosed by the instant specification, the 4-nerolidylcatechol is present within such a composition only in the form *Pothomorphe umbellata* extract (i.e., a "standardized extract") which contains this compound therein (within the recited percentage amounts) - but not in the form of an isolated compound taken (extracted) from the *Pothomorphe umbellata* plant.

Applicant is required to cancel the new matter in the reply to this Office Action - or alternatively, to particularly point to adequate support for the above discussed claim limitations, in response to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 and 29 are rendered vague and indefinite by the phrase "wherein the 4-nerolidylcatechol is naturally occurring". It is unclear as to what is actually meant by the phrase "naturally occurring" - e.g., in what way is the recited compound "naturally occurring"?

Claims 26 and 30 are rendered vague and indefinite by the phrase "the 4-nerolidylcatechol is extracted from *Pothomorphe umbellata*". Is this phrase attempting to define that the 4-nerolidylcatechol is isolated/separated from the *Pothomorphe umbellata* plant (which is also deemed new matter - as discussed above), that the 4-nerolidylcatechol is within an extract of the recited plant, or something else?

Claim 28 is rendered vague and indefinite by the overall phrase "topical administration of a gel of the composition:" (line 2) because it is unclear as to who or what the composition is being administered to - e.g., the skin of an animal/human (such as in need thereof), to a skin cell culture, to a table top, or something else? Further, it is unclear as to what is meant by the phrase therein "a gel of the composition". In addition, the limitation therein "the composition" lacks sufficient antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ropke et al. (Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527, 15 July 2002) and Ropke et al. (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000 - including entire English Translation of this document) in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art.

The two cited Ropke et al. references each beneficially teach a topical gel compositions having strong therapeutic antioxidant activity which comprises an extract of *Pothomorphe umbellata*, whereby the gel compositions comprises 4-nerolidylcatechol (on the basis of the *Pothomorphe umbellata* extract). In addition, the second Ropke et al. reference (2000) discloses a topical compositions presented in a gel form (i.e., within diadermine - an oil/water emulsion) comprising an extract of *Pothomorphe umbellata*, whereby the topical compositions comprises 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein; and further that the dry extract contains 2.35% of 4-nerolidylcatechol therein (see, e.g., page 8 of English translation) - thus, apparently within the instantly claimed ranges therein. The cited Ropke et al. references also teach topically applying the gel compositions to the skin of hairless mice (see Abstract# S527 of first Ropke et al. reference; and entire English translation including pages 2-5, 7-9,13-14, 16, and final paragraph on page 18 of the second Ropke et al. reference). Neither of the Ropke et al. references expressly teaches providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 - col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use - such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the *Pothomorphe umbellata* extract preparation having strong therapeutic antioxidant activity as taught by each of the Ropke et al. references into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) - including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such conventional ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please note that the topical application of such an extract gel preparation would intrinsically provide one or more of the functional effects instantly claimed, including with respect to preventing such skin afflictions.

Thus, the invention as a whole was clearly *prima facie* obvious over the references (and, if necessary, the admitted state of the art) especially in the absence of clear and convincing evidence to the contrary.

Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchiyama et al. (JP 2001122763 - full computer-assisted English translation enclosed) in view of Barros et al. (Ciencia e Cultura, 1996) and Desmarchelier et al. (Planta Med, 1997), and further in view of Wheeler (US 6,165,479) and, if necessary, the admitted state of the art.

Uchimyama et al. beneficially teach a topical skin composition (e.g., in the form of a lotion, cream, etc.) comprising an extract of *Pothomorphe umbellata*.(including an alcoholic extract such as an ethanolic or methanolic extract - please note, as evidenced by Barros et al. and Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally occurring compound 4-nerolidylcatechol) as an active skin therapeutic ingredient therein (e.g., useful against skin aging caused by ultraviolet rays among other therapeutic effects), as well as topically applying such a composition to the skin. Uchimyama et al. also beneficially teach that the extract composition has antioxidant activity (i.e., oxygen-eliminating ability) - such as instantly disclosed (see entire English translation including paragraphs [0007] - [0016], [0021], [0028], [0034]-0035], [0037], and Tables).

The Barros et al. and Desmarchelier et al. references each beneficially teach a composition comprising an alcoholic (ethanolic - Barros et al; methanolic - Desmarchelier et al) extract of *Pothomorphe umbellata* - whereby the extracts demonstrate strong antioxidant activity (such as instantly disclosed) which contain the compound 4-nerolidylcatechol - apparently within

the instantly claimed percentage range (as best understood) - therein (see entire documents including *Abstract* and *Materials and Methods*).

None of the above references, including Uchimyama et al., expressly teach providing the skin therapeutic *Pothomorphe umbellata* extract within a skin gel composition - including one containing carboxymethylcellulose, propylene glycol, and methylparaben, as instantly claimed.

Wheeler beneficially teaches that carboxymethylcellulose, propylene glycol, and methylparaben are well known conventional ingredients within skin therapeutic compositions such as skin gels, including those containing an antioxidant therein (see entire reference including col 2, line 58 - col 4, line 67). Further, as readily admitted by Applicants, the instantly claimed dermocosmetic composition can be prepared in accordance with prior art methods for topical use - such as one containing carboxymethylcellulose, propylene glycol, and methylparaben (see, e.g., page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate an alcoholic (e.g., ethanolic or methanolic) extract of *Pothomorphe umbellata* within the skin therapeutic composition (having antioxidant activity) as taught by Uchimyama et al, especially since Uchimyama et al. beneficially teaches that ethanolic and methanolic solvents are effective solvents to employ, and Barros et al. and Desmarchelier et al. beneficially teaches that such alcoholic solvents provide a *Pothomorphe umbellata* extract having strong antioxidant activity (in addition, it should again be noted that, as evidenced by Desmarchelier et al., such an alcoholic extract would inherently comprise the naturally-occurring compound 4-nerolidylcatechol therein). It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate such a *Pothomorphe*

umbellata extract into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) - including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler, as well as (if necessary) the admitted state of the prior art, with respect to their well known conventional use therein, as discussed above. Accordingly, the adjustment of this and other types of conventional working conditions (e.g., determining an appropriate amount range of such ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole was *prima facie* obvious over the references (and, if necessary, the admitted state of the art) especially in the absence of clear and convincing evidence to the contrary.

Applicants' arguments over the art rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections.

At the outset, Applicants argue that one of the references cited in the first USC 103 above (i.e., Ropke et al., Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527 - published 15 July 2002) should not be considered prior art since it was published by the inventors themselves within the grace period of the present Application based upon the Brazilian priority applicant which was filed 18 September 2002. However, please note that 18 September 2002 is the earliest effective date Applicants are entitled to (with an English translation thereof). Since the Ropke et al. reference of 15 July 2002 precedes this date, it properly constitutes prior art over the

instantly claimed invention (further, as an aside, please note that the Ropke et al. reference of 15 July 2002 list many more authors than the number of inventors on the instant Application and, thus, the Ropke et al. reference of 15 July 2002 is not of the same inventive entity as instantly disclosed). Applicants further argue that no relevant prior reference teaches a gel composition comprising 0.005 to 20.0% of 4-nerolidylcatechol therein. However, the Ropke et al. reference of 15 July 2002 expressly discloses a gel composition (as discussed *supra*). Applicants also argue that the Ropke reference of 2000 (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000) does not teach a topical composition in a gel form as previously suggested by the Examiner. However, (as discussed in the first USC 103 rejection above), the Ropke et al. reference of 2000 discloses topical compositions presented within diadermine - an oil/water emulsion, which reasonably reads upon a "gel composition" as instantly claimed, whereby the composition comprises an extract of *Pothomorphe umbellata* containing 0.2%, 0.05, 0.1, 0.2, and 2% (p/p) of 4-nerolidylcatechol therein.

Applicants further argue that some of the prior art cited by the Examiner - such as Uchiyama (JP 2001122763), also makes reference to *Pothomorphe umbellata* extracts but do not teach a composition specifically containing 4-nerolidylcatechol, nor do they teach therapeutic methods of topically administration of a gel composition thereof. However (as discussed *supra*), as evidenced by Barros et al. and Desmarchelier et al., such an alcoholic extract (as the *Pothomorphe umbellata* alcoholic extract within the topical skin composition taught by Uchiyama) would inherently comprise the naturally occurring compound 4-nerolidylcatechol) as an active skin therapeutic ingredient therein, which Uchiyama discloses is therapeutically useful

(including as an antioxidant) against skin aging caused by ultraviolet rays among other therapeutic effects, as well as topically applying such a composition to the skin.

With respect to other generalized statements and/or arguments made by Applicants over various prior art references cited within the USC 103 rejections above, Applicants have argued and discussed some of the references individually without clearly addressing the combined teachings (further, please note that some of the cited references within the art rejections above, including the admitted state of the art discussed therein, were not addressed in Applicants arguments). It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655